EXHIBIT 61

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 526-6000 Fax:(973) 526-6069	07/10/2006 - 08/10/2006* FEI NUMBER 2244683

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Divya Patel, President

FIRM NAME	STREET ADDRESS
Actavis Totowa LLC	101 E Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Little Falls, NJ 07424-5608	Pharmaceutical Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically, there is no assurance that the Quality Unit can be relied upon to fulfill its responsibilities to assure that all drug products released to the marketplace meet the requirements for identity, strength, quality, and purity that they purport to have. Batches of drug products that initially failed to meet release specifications were released into interstate commerce without being fully investigated, all laboratory data was not included with the batch records and manufacturing deviations were not always documented.

OBSERVATION 2

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically, the Quality Unit failed to assure that laboratory notebooks include all data generated during testing and that analysts document in their laboratory notebook all sample preparation and testing at the time it occurs. Additionally, SOP QC-59 Investigation of out of specification test Results (OOS) is not always followed. For example:

a) On 1/11/06, during content uniformity testing of Ursodiol Capsules, batch 51083A, the analyst noticed that the first two capsules were out of specification and he aborted the run. The audit trail for the laboratory data acquisition system does not indicate that the run was aborted and the analyst did not print the sample results or report the failing results in the laboratory notebook. An investigation was initiated and it concluded that a sample dilution error was made. A review of the lab notebook shows the sample dilution value in the laboratory notebook was over written, without being signed and dated as required. Additionally, a review of the laboratory notebook page showing the sample preparation and a photocopy of the same page in the investigation repot, revealed that they were not the same. Changes were made in the laboratory notebook after is was signed and approved.

b) The original result of 66.5% for Sample 1-1 for pooled dissolution of Oxycodone and Acetaminophen Capsules Batch # 5259A was not documented in [redacted] and was not attached to the hard copy

SEE REVERSE OF THIS PAGE	Kristy Kellis, Investigator Nancy Kelly Investigator	DATE ISSUED 08/10/2006

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chromatograms. An additional injection was made for Sample 1-1 within the same chromatographic run and was used in the calculations. The original result had not been invalidated.

c) The original result of 77.7% for Capsule-2 dissolution sample for Amidrine Capsules, Batch # 5637A, was not documented in [redacted]. An additional injection was made for Capsule-2 within the same chromatographic run and was used in the calculations. The original result had not been invalidated.

d) Quinapril batch # 60423A was tested on 5/31/06 and failed to meet the specification for impurities. A new sample preparation was prepared and the batch was retested within the same chromatographic run, without prior approval as required. The original results and the results of the new sample preparation appear together in the laboratory notebook not one after the other. The out of specification (OOS) results for high impurities were invalidated without any scientific justification and the batch was retested and released. This same batch had a low yield due which was attributed to compression problems. The entire batch was compressed below the action limit for hardness, which resulted in the rejection of approximately 50,220 broken tablets, or 4.25 % of the batch.

e) The original result of 89.9% for Assay-1 in the analysis of Buspirone HCl 5 mg Tablets Batch # 3144A, 24 month stability was not documented in [redacted]. An additional injection was made for Assay-1 within the same chromatographic run and was used in the calculations. The original result had not been invalidated.

f) There was no notation in [redacted] although the original result for Assay-1 of Amidrine Capsules Batch # 5113A did not show any peaks (due to injection of the wrong vial). An additional injection was made and results were recorded without documenting the discrepancy. A note was later squeezed into the Laboratory Notebook just above the "Conclusion" section of the analysis.

g) On 10/7/05 during the testing of Hyoscyamine Sulfate Tablets, batch 5823A, one assay value was approximately double the expected value. The failing results were attributed to a transcription error in the sample weight. The failing results were not recorded in the laboratory notebook and were not printed from the laboratory data acquisition system.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, there is no assurance that the Quality Unit can detect discrepancies in reports for which they are responsible. Data and reports reviewed and approved by the Quality Unit were not accurate and complete and did not adhere to established procedures. In addition, changes are not always documented in the change control system. For example:

a) A page was left blank in [redacted] between the original and repeat testing of Carisoprodal, Aspirin and Codeine Tablets, Batches 2020A, A1, 36-month stability samples and 3027A1, 12-month stability samples, for Codeine Phosphate Assay. The page was later written on by the Director of QC indicating why the previous results had been disqualified.

b) The Process Validation Report for Ursodiol Capsules USP 300 mg [redacted] dated 6/23/06, did not mention the OOS result received during the Content Uniformity testing of Batch 51083A.

c) The Process Validation Report for Hydroxyzine HCl USP 50 mg [redacted] dated 8/9/05, did not mention the OOS result received during the Blend Assay testing of Batch # 5519A.

d) The current inventory of the exhibit batch listed in [redacted] Benztropine Mesylate 2 mg Tablets states "RBR-1661: 7667 tablets stored for bulk stability evaluation." The exhibit batch for Benztropine Mesylate 2 mg Tablets is RBR 2137. RBR-1661 is the exhibit batch for Hydroxyzine HCl. Additionally, the results for bulk

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stability of Benztropine Mesylate reflect that of the testing of finished packaged product and not that of the bulk (see Observation # 7)

e) The compression page of the batch record for Quinipril was changed to add a statement about timeframes and how to pack the blend. This change did not go through the change control system.

LABORATORY CONTROL SYSTEM

OBSERVATION 4

Written records are not always made of investigations into the failure of a batch or any of its components to meet specifications.

Specifically, investigations were not conducted when out of specification (OOS) results were generated. Samples were retested and the original results were not invalidated. For example:

a) No initial investigation was made into the out of specification Assay-1 result for Buspirone HCl 5mg Tablets Batch # 3144A, 24-month stability (result was 89.9%), when the result was obtained on 3/20/05. Assay-1 was repeated within the same chromatographic run. There was no documented investigation until 7/15/05 and retesting did not include a re-injection of the same sample vial.

b) No initial investigation was made into the out of specification result for the Left-Slope Blend Assay sample of Hydroxyzine HCl Tablets, 50 mg Batch # 5519A (result was 110.2%), when the result was obtained on 6/24/05. The analysis of the Left-Slope sample was repeated within the same chromatographic run. There was no documented investigation until 7/27/05 and retesting did not include a re-injection of the same sample vial.

c) No initial investigation was made for an out of specification assay result for Quinapril HCl and Hydrochlorothiazide Tablets, 10/12.5 mg, Batch # 4180A1, 12-month stability (result was 111.2%), when the result was obtained on 5/24/05. The analysis was repeated with new sample solutions within the same chromatographic run. There was no documented investigation until 7/22/05, which indicated that the sample solutions were prepared using the average tablet weight instead of twice the average tablet weight, which resulted in peak areas of approximately 50% of the standard response. This explanation should not have resulted in an OOS result. The investigation did not address the OOS result generated.

d) No initial investigation was made for an out of specification blend uniformity result for Oxycodone HCl Tablets, 15 mg, Batch # 5023A (result 110.2%), when the result was obtained on 1/14/05. The analysis was repeated within the same chromatographic run. There was no documented investigation until 7/13/05.

e) No initial investigation was made for the out of specification result of 65.5% for Sample 1-1 for pooled dissolution of Oxycodone and Acetaminophen Capsules Batch # 5259A, when the result was obtained on 4/14/05. An additional injection was made for Sample 1-1 within the same chromatographic run and was used in the calculations. The original result had not been invalidated and there was no documented investigation until 7/19/05.

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OBSERVATION 5

Input to and output from the computer are not checked for accuracy.

Specifically, audits were not conducted of the TotalChrom Data Acquisition System used to run the HPLC instruments during analysis of drug products. Sample injections, processing methods, and sample weights were not reviewed or verified for the accuracy of reported sample results during testing of in-process, finished product and stability samples.

OBSERVATION 6

The suitability of all testing methods is not verified under actual conditions of use.

Specifically, there is no assurance that equipment is adequately cleaned due to the deficiencies in cleaning validation studies. For example:

a) Cleaning validation was performed for the process trains of the following products without evaluating for sample recovery: Amidal Nasal Decongestant Tablets, Amigesic Caplets 750 mg, Carisoprodol and Aspirin Tablets USP 200 mg/325 mg, Carisoprodol Tablets USP 350 mg, Chlorzoxazone Tablets USP 250 mg and 500 mg, Digoxin Tablets USP 0.25 mg, Guanfacine Tablets USP 2 mg, Meperidine Hydrochloride Tablets USP 100 mg and 50 mg CII, Pemoline Tablets 75 mg CIV, Phentermine Hydrochloride Capsules USP 30 mg and 37.5 mg CIV, Ursodiol Capsules USP 300 mg. (This list is not all inclusive.)

b) Recovery studies were performed by applying a known amount of active pharmaceutical ingredient directly to a swab instead of applying the active to a coupon or template to replicate the equipment surface from which the active should have been swabbed. Cleaning validation was performed in this manner for the process trains of the following products: Buspirone Hydrochloride Tablets USP 5mg, 10 mg and 15 mg, Hydrocodone Bitartate and Homatropine Methylbromide Tablets 5mg/1.5mg, Mirtazapine Tablets 45 mg, Oxycodone and Acetaminophen Capsules USP 5 mg/500 mg, Oxycodone Hydrochloride Tablets USP 15 mg and 30 mg, Pemoline Tablets 18.75 mg CIV, Pentazocine Hydrochloride and Acetaminophen Tablets 25 mg (base) and 650 mg CIV, Quinaretic (Quinapril HCl and Hydrochlorthiazide Tablets) 20 mg/ 25 mg. (This list is not all inclusive.)

c) Cleaning Validation studies do not indicate whether or not a cleaning agent was used when cleaning the equipment process train. Equipment cleaning SOPs prior to March 2006 indicated that equipment could be cleaned "using hot water or with approved cleaning agent and water if necessary". In addition, there are no studies to show the cleaning agent is effectively removed from equipment during the cleaning process.

d) The method for cleaning verification of Benztropine Mesylate was used on 4/28/05 to analyze for residual active after the production of Benztropine Mesylate Tablets RBR-2136 (1 mg) and RBR-2137 (2 mg) although the method was not evaluated for specificity until 5/9/05.

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OBSERVATION 7

The written stability testing program is not followed.

Specifically, the stability data recorded as that of bulk stability hold time studies are actually obtained from the testing of the following packaged finished products:

Benztropine Mesylate Tablets, USP 0.5 mg, 1 mg, 2 mg
Buspirone Hydrochloride Tablets, USP 30 mg
Imipramine Hydrochloride Tablets, USP 10 mg, 25 mg, 50 mg
Methimazole Tablets, USP 5 mg, 10 mg
Phendimetrazine Tartrate Tablets, USP 35 mg

PRODUCTION SYSTEM

OBSERVATION 8

Examination and testing of samples is not done to assure that in-process materials conform to specifications.

Specifically, on numerous occasions quality assurance personnel failed to detect tablets and capsules which did not meet in-process specifications for tablet weight and thickness. SOP-016, "Routine Tablet Press Overcheck", requires a new set of samples be taken when out of specifications results are encountered, this did not occur. For example:

a) On 7/15/05, during the compression of Carisoprodal Tablets, batch 5564A, one tablet was documented as having an out of specification value of 5.9 kp for hardness on the "QA In-Process Compression Overcheck Data Sheet". The hardness specification is [redacted]. The OOS tablet was discovered on 5/19/06, during the compilation of data for the Annual Product Review. Additional tablets were not tested as required by SOP QA-16 and no tablets were rejected which may have been required.

b) On 11/21/05, during the compression of Carisoprodol , Aspirin & Codeine Tablets, batch 5904A, one tablet was documented as having an out of specification value of 8.9 kp for hardness on the "QA In-Process Compression Overcheck Data Sheet", the hardness specification [redacted]. The out of specification tablet was discovered on 4/26/06, during the compilation of data for the Annual Product Review. Additional tablets were not tested as required by SOP QA-16 and no tablets were rejected which may have been required.

c) On 8/13/05, during the compression of Quinaretic (Quinapril HCL and HCTZ) Tablets, batch 5659A , one tablet was documented as having an out of specification hardness value of 7.2 kp on the "QA In-Process Compression Overcheck Data Sheet" the hardness specification [redacted]. The out of specification tablet was discovered on 5/19/06, during the compilation of data for the Annual Product Review. Additional tablets were not tested as

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required by SOP QA-16 and no tablets were rejected which may have been required.

d) On 5/19/05, during the compression of Meclizine Hydrochloride Chewable Tablets, batch 5352A, one tablet was documented as being out of specification for weight and no action was taken. The tablet weight was documented, as .237 gm on the "QA In-Process Compression Overcheck Data Sheet" the weight specification is .209 gm to 0.231 gm. The out of specification tablet was not investigated until 12/08/05, when it was discovered during the compilation of data for the Annual Product Review. Therefore, additional tablets were not tested as required by SOP QA-16 and no tablets were rejected which may have been required. On 8/16/05, during the compression of Phenazopyridine Hydrochloride Tablets, batch 5678A, one tablet was documented as being out of specification for weight. The tablet weight was documented as .344 gm on the "QA In-Process Compression Overcheck Data Sheet" and the weight specification is .346 gm to 0.402 gm. The out of specification tablet was not investigated until 6/16/06, when it was discovered during the compilation of data for the Annual Product Review. Therefore, additional tablets were not tested as required by SOP QA-16 and no tablets were rejected which may have been required.

OBSERVATION 9

Deviations from written production and process control procedures are not recorded and justified.

Specifically, there is no assurance that all manufacturing deviations are documented. For example:

a) On 11/8/05, Mirtazapine OD Tablets were observed to contain black specks during tablet inspection. Investigation 05-013, into the black specks states that during compression the operators observed the product sticking to the punch tips. The operator was instructed by the supervisor to remove and clean the upper and lower punches and then polish the punch tips. The dies and feed frame were also removed and cleaned. None of this was documented on the "Compression Data Sheet" which shows no problems were encountered in compression.

b) On 5/19/06, during the compression of Quinapril HCL Hydrochloprothiazide Tablets, batch 60423A, tablets were compressed below the action limit of 7.0 kp. The "Compression Data Sheet" does not indicate that there were any problems with compression although the entire batch was compressed at a range of 4.4kp -6.1 kp which is below the target tablet hardness of [redacted] and below the action limit of [redacted]. An investigation for this batch was not initiated until 6/2/06 when the batch did not meet yield specifications. The low yield was attributed to broken tablets.

c) Deviation 05-11 was generated when Pentazocine HCL & Naloxone HCL Tablets, batch RBR2104 could not be compressed at the required tablet hardness specification of 6-13 kp, on 4/27/05. Compression was stopped and a supplement was filed with FDA to change the hardness specification to [redacted]. There is no "QA In-Process Compression Start Up Data Sheet" dated 4/27/06. The only compression start up sheet is dated 5/4/06 which is updated with the new tablet hardness specification of [redacted]

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OBSERVATION 10

The master production and control records are deficient in that they do not include complete sampling and procedures.

There is no assurance that all in-process blend samples collected from the mixer are 1 x 3 times the tablet/capsule weight as required. The sample collection is not documented and the sample weight is not measured. For example:

The QA submission form, which is submitted to the laboratory with the in-process blend uniformity samples, does not include the sample weights and the collection of the samples is not recorded in the batch record.

FACILITIES & EQUIPMENT SYSTEM

OBSERVATION 11

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically, equipment qualifications are deficient in that acceptance criteria are not specified, and discrepancies are not documented. For example:

a) The Re-Qualification of the Stokes BB2 Tablet Press, Equipment ID # 70, which was used in the production of Benztropine Mesylate Tablets, Batch # RBR-2137, does not have clearly defined acceptance criteria. In addition, there is no discrepancy report to explain why equipment drawings, equipment schematics, equipment manuals and purchase orders were not available, what steps had been taken in an attempt to obtain these materials and why this was acceptable.

b) The specified utility requirements were not met in the equipment re-qualification for Fitzmill ID # 12, which was used in the production of Benztropine Mesylate Tablets, Batch # RBR-2137. The specification for voltage was [redacted] Volts, but the actual voltage is 208 Volts. There is no discrepancy report to explain why this failure to meet the specification is or is not acceptable.

c) There are no equipment qualifications for the Lydon Brothers Inc. Drying Oven ID # 271 or the Blue M Drying Oven ID # 273. These ovens are used in the production of Benztropine Mesylate Tablets as well as more than fifteen other products.

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OBSERVATION 12

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, there is no assurance that preventative maintenance is conducted for equipment at scheduled intervals. For example:

a) Duct tape was observed on the feed throat of Fitzmill #12 during the tour of manufacturing operations.
b) There are no preventative maintenance programs for the Lydon Brothers Inc. Drying Oven ID # 271 or the Blue M Drying Oven ID # 273.
c) Preventative Maintenance is to be conducted on Double Cone Blender ID # 41 every six months according to DOI # PRD-011: Blenders - Preventative Maintenance and Repairs." However, no maintenance had been conducted between 1/8/04 and 12/8/04 or between 5/12/05 and 5/19/06.

MATERIALS SYSTEM

OBSERVATION 13

Rejected in-process materials are not identified and controlled under a quarantine system to prevent their use in manufacturing or processing operations for which they are unsuitable.

Specifically, rejected batches are not labeled as rejected or placed in a section of the warehouse for rejected products. For example:

a) Acetaminophen/Caffeine/Dihydrocodeine/Bitrartrate Tablets, batch RBR2526 was rejected on 3/17/06, when the final blend uniformity samples failed to meet specifications. On 7/13/06, this batch was not labeled as rejected and was in the WIP (work in progress) Warehouse, labeled as "In-Process".
b) Cyclobenzaprine HCL Tablets, batch 5846 was rejected on 10/7/05, when blend uniformity samples failed to meet specifications. On 7/13/06, this batch was not labeled "rejected" and was found in the WIP (work in progress) warehouse, labeled as "In-Process".
c) Dantrolene Sodium Capsules, batches 60220A, 60228A and 60229A, were rejected on 5/17/06, when final blend uniformity samples failed to meet specifications. On 7/13/06, this batch was not labeled as rejected when it was found in the in the WIP (work in progress) Warehouse.

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OBSERVATION 14

Written procedures are not followed for the receipt and storage of components.

Specifically, all locations are not identified throughout the warehouse as required by Departmental Operating Instructions (DOI) PRD-068: "Raw Material Locator System", nor are they recorded on Material Inventory Cards as required by DOI PRD-066: "Receiving Raw Materials & Packaging Components," to describe where materials are located in the warehouse. For example:

a) Magnesium Hydroxide PO # 60875 was observed in the warehouse in an unidentified location. There was no location filled out on the Material Inventory Card.
b) Unitab Microcrystalline Cellulose PO # 60134-6 was observed in the warehouse in an unidentified location. There was no location filled out on the Material Inventory Card.

OBSERVATION 15

There was a failure to handle and store components at all times in a manner to prevent contamination.

Specifically, all raw materials for a batch are weighed in the manufacturing room without cleaning between the dispensing of each ingredient. The cleaning log for the room only reflects the cleaning of the room after the production of the batch. In addition, procedures do not indicate that the active ingredient should be the last material to be weighed.

* DATES OF INSPECTION:
07/10/2006(Mon), 07/11/2006(Tue), 07/12/2006(Wed), 07/13/2006(Thu), 07/14/2006(Fri), 07/18/2006(Tue), 07/19/2006(Wed), 07/20/2006(Thu), 07/21/2006(Fri), 07/25/2006(Tue), 07/26/2006(Wed), 07/31/2006(Mon), 08/01/2006(Tue), 08/10/2006(Thu)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Kristy A. Zielny, Investigator

Nancy L. Rolli, Investigator

RELEASE

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REVIEWED BY AZ C.O. 1/4/08 DATE

DATE ISSUED 08/10/2006